TranS1

Response for K073643

**Premarket Notification [510(k)] Summary**
Prepared: March 31, 2008

APR 2 8 2008

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations, Part 807, and in particular 807.92, the following summary of information is provided:

**Submitter Information**

TranS1 Incorporated
411 Landmark Drive
Wilmington, NC 28412

**Application Contacts:**

Robert Sheridan
Senior Advisor to TranS1 Inc.
Same address and fax as above
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Bill Jackson
Vice President of Regulatory, Clinical, and Quality
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bjackson@trans1.com

**Device Names**

| | |
|---|---|
| Proprietary Name: | TranS1® AxiaLIF® II System |
| Common/Usual Name: | Anterior spinal fixation system |
| Classification Name: | Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060) |
| Regulatory Classification | Class II |
| Product Code: | KWQ |
| FDA Panel Code: | 87 Orthopedics |

**Device Description**

The TranS1® AxiaLIF® II System is made of medical grade titanium alloy conforming to such standards as ASTM F-136.

**Intended Use and Indications for Use**

TranS1® AxiaLIF® 2-LEVEL System is intended to provide anterior stabilization of the L4-S1 spinal segments as an adjunct to spinal fusion. The AxiaLIF® 2-LEVEL System is also intended for minimally invasive access to the anterior portion of the lower spine for assisting in the treatment of degeneration of the lumbar disc, performing lumbar discectomy, or for assistance in the performance of L4-S1 interbody fusion.

The AxiaLIF® 2-LEVEL System is indicated for patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (Grade 1), or degenerative disc disease as defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The AxiaLIF® 2-LEVEL System is not intended to treat severe scoliosis, severe spondylolisthesis (Grades 2, 3 and 4), tumor, or trauma. The device is not meant to be used in patients with vertebral compression fractures or any other condition where the mechanical integrity of the vertebral body is compromised. Its usage is limited to anterior supplemental fixation of the lumbar spine at L4-S1 in conjunction with legally marketed facet or pedicle screw systems.

**Substantial Equivalence**

Documentation was provided to demonstrate that the TranS1® AxiaLIF® II System is substantially equivalent to the TranS1® AxiaLIF® System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

TranS1 Incorporated
% Mr. Robert Sheridan
Senior Advisor to TranS1 Inc.
411 Landmark Drive
Wilmington, NC 28412

APR 28 2008

Re: K073643
Trade/Device Name: TranS1® AxiaLIF II
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: April 22, 2008
Received: April 23, 2008

Dear Mr. Sheridan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Statement of Indications for Use**

510(k) Number: K073643

Device Name: TranS1® AxiaLIF II

Indications for Use:

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| Prescription Use ___X____ (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
|---|---|---|

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Phil RP Dyden for mxm

**(Division Sign-Off)**



**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K073643